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**SHERLEY V. SEBELIUS: A CALL TO CONGRESS TO EXPLICITLY  
SUPPORT MEDICAL RESEARCH ON HUMAN EMBRYONIC STEM  
CELLS**

*Layla Cummings\**

*Progressive biomedical research is the key to developing new and effective treatments for many of the diseases and conditions that afflict our society. The scientific community is in agreement that human embryonic stem cell research is a field that holds great promise. The recent federal district court opinion in Sherley v. Sebelius threatens to derail the progress of science and the hope of millions by denying federal funding of this research based on an appropriations rider known as the Dickey-Wicker Amendment. While the rider's plain language bans federal funding of any research that creates or destroys embryos, it has been accepted for over a decade that the government may fund research on stem cell lines that are obtained through private funding. With an uncertain outcome pending in the Court of Appeals, it will be argued that the Dickey-Wicker Amendment should be amended or repealed to give effect to the longstanding practice by the National Institutes of Health of funding human embryonic stem cell research within ethical guidelines. Furthermore, Congress should make it a priority to pass the Stem Cell Research Advancement Act in order to explicitly support the efforts of scientists working with human embryonic stem cells to develop groundbreaking medical advances.*

**I. INTRODUCTION**

Embryonic stem cell research has been a divisive political and social issue since its inception. It provides hope of progressive new treatments to the millions suffering from devastating medical conditions, such as diabetes, heart disease, vision and hearing loss,

and spinal cord injuries.<sup>1</sup> Unfortunately, since embryonic stem cell research involves the destruction of human embryos, it also stirs intense debate mainly focused on the moral status of days old embryos.<sup>2</sup> In late August of 2010, a federal district court judge sent the medical research community into a panic by declaring that federal funding of embryonic stem cell research is contrary to federal law.<sup>3</sup> In *Sherley v. Sebelius*, Judge Royce Lamberth relies on an appropriations rider known as the Dickey-Wicker Amendment (“Amendment”)<sup>4</sup> to strike down new guidelines developed by the National Institutes of Health (“NIH”). These guidelines were designed to increase the quantity of embryonic stem cell lines available for medical research purposes.<sup>5</sup>

The technique to isolate and grow stem cells from human embryos was first perfected in 1998 by researchers at the University of Wisconsin.<sup>6</sup> In the decade since the scientific breakthrough was made, the issue has garnered attention from conservatives and liberals alike. The first federal funds to go towards human embryonic stem cell research were approved by President George W. Bush, albeit with significant restrictions.<sup>7</sup> Under President Obama, support for embryonic stem cell research was to be expanded by an executive order that would lift the

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<sup>1</sup> *Stem Cell Information: Stem Cell Basics*, NAT’L INSTS. HEALTH, 8, <http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf> (last modified Apr. 28, 2010).

<sup>2</sup> James F. Childress, Ph.D., *An Ethical Defense of Federal Funding for Human Embryonic Stem Cell Research*, 2 YALE J. HEALTH POL’Y, L. & ETHICS 157, 160 (2001).

<sup>3</sup> *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 73 (D.D.C. 2010).

<sup>4</sup> See Omnibus Appropriations Act 2009, Pub. L. No. 111-8, § 509(a)(2), 123 Stat. 524, 803 (2009); See also Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

<sup>5</sup> National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32170 (July 7, 2009).

<sup>6</sup> See *Stem Cell Information: Frequently Asked Questions*, NAT’L INSTS. HEALTH, <http://stemcells.nih.gov/info/faqs> (last modified Aug. 2, 2010).

<sup>7</sup> Exec. Order No. 13,435, 3 C.F.R. 222 (2007).

restrictions put in place by President Bush.<sup>8</sup> Despite a change in executive policy, the district court decision in *Sherley v. Sebelius* demonstrates that President Obama may not be able to expand embryonic stem cell research without the support of Congress.

Part II of this Recent Development briefly discusses the current state of stem cell research and sets the foundation for the argument that embryonic stem research should continue as a means of ultimately providing effective treatment to life-threatening conditions and diseases. Part III discusses the regulatory framework surrounding stem cell research in the United States, the holding reached in *Sherley v. Sebelius*, and the rationale behind the decision. Part IV recommends that Congress act to amend or repeal the Dickey-Wicker Amendment as well as pass legislation codifying President Obama's executive order, which called for the expansion of stem cell research within a responsible ethical framework.<sup>9</sup>

## II. THE BASICS OF STEM CELL RESEARCH

### A. *What Are Stem Cells?*

Stem cells are important for research purposes because, unlike other cells, they are undifferentiated. This means that they have yet to transform into the many different types of cells in the body.<sup>10</sup> There are three basic types of human stem cells: 1) embryonic stem cells ("hESCs"); 2) adult stem cells ("ASCs"); and 3) induced pluripotent stem cells ("iPSCs").<sup>11</sup> Human embryonic stem cells are typically derived from pre-implantation stage embryos<sup>12</sup> and are pluripotent, meaning they have the ability to divide into almost any

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<sup>8</sup> President Obama fulfilled his promises to expand the scope of federal funding of stem cell research with an executive order issued in 2009, during his first year in office. See Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (2009).

<sup>9</sup> *Id.*

<sup>10</sup> *Stem Cell Information: Frequently Asked Questions*, *supra* note 6. Stem cells are undifferentiated cells that have yet to acquire a specialized function. *Id.*

<sup>11</sup> See *Stem Cell Information: Stem Cell Basics*, *supra* note 1, at 2.

<sup>12</sup> These embryos are usually the leftover embryos from *in vitro* fertilization procedures that would have been discarded otherwise. See *id.* at 8.

type of cell in the body.<sup>13</sup> Pluripotent cells provide a unique glimpse into the study of cell development and are a potential source for new replacement cells and tissues to be used in medical treatments.<sup>14</sup> Adult stem cells are cells found in organs and tissues and are multipotent, meaning they are further differentiated than hESCs but they can still be specialized into a few different cell types.<sup>15</sup> The area of the body where the particular adult stem cell originated (i.e. the heart, bone marrow, blood) generally limits the research value of ASCs.<sup>16</sup> Research on ASCs has been conducted since the 1950s and is accepted as uncontroversial because it involves adult donors, not embryos.<sup>17</sup> The third type of stem cell, induced pluripotent stem cells, are adult cells that have been “genetically reprogrammed to an embryonic stem cell-like state.”<sup>18</sup> Research on human iSPCs began in late 2007 and is a promising new area of research that may lead to the same type of potential for medical treatments as hESCs.<sup>19</sup>

#### B. *The Significance of Human Embryonic Stem Cell Research*

Currently, federal funding supports all three types of stem cell research.<sup>20</sup> There have been policy arguments made that question the necessity of human embryonic stem cell research when adult stem cell research is successful and induced pluripotent stem cell research may provide similar benefits. However, an argument in

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<sup>13</sup> *Stem Cell Information: Frequently Asked Questions*, *supra* note 6 (“Pluripotent stem cells can give rise to any type of cell in the body except those needed to support and develop a fetus in the womb.”)

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Stem Cell Information: Stem Cell Basics*, *supra* note 1, at 4.

<sup>17</sup> See Stephen R. Latham, *The Once and Future Debate on Human Embryonic Stem Cell Research*, 9 YALE J. HEALTH POL’Y L. & ETHICS 483, 485 (2009) (“Adult stem cell research (and, for the most part, embryonic stem cell research conducted in laboratory animals) has been fairly uncontroversial.”).

<sup>18</sup> *Stem Cell Information: Frequently Asked Questions*, *supra* note 6.

<sup>19</sup> *Stem Cell Information: Stem Cell Basics*, *supra* note 1, at 13–14.

<sup>20</sup> *The Promise of Human Embryonic Stem Cell Research: Hearing on the Promise of Embryonic Stem Cell Research before S. Subcomm. on Labor, Health and Human Services, Education, and Related Agencies of the S. Comm. on Appropriations*, 111th Cong. 4–5 (2010) [hereinafter *Hearing*] (statement of Dr. Francis Collins, Director, National Institutes of Health).

favor of abandoning human embryonic stem cell research for adult stem cell and induced pluripotent stem cell research is shortsighted.<sup>21</sup> The reasoning against using exclusively adult stem cells to conduct such research is simple: as multipotent cells, ASCs have limited utility.<sup>22</sup> Adult stem cells do not have the flexibility to turn into almost any of the cells of the body, as hESCs and iPSCs can when manipulated by researchers.<sup>23</sup> Additionally, hESCs are capable of “long-term self renewal,”<sup>24</sup> allowing them to continue dividing without becoming differentiated for months or even years, whereas most adult stem cells cannot perform this function.<sup>25</sup> Long-term self-renewal allows researchers to experiment on these particular lines of cells, which will help them understand more and gain an understanding of the cellular regulatory process, which could prove valuable for treatment purposes.<sup>26</sup>

The abandonment of hESC research may also be premature because induced pluripotent stem cell research is in its infancy and human embryonic stem cells are still the “gold standard.”<sup>27</sup> With only a few years of research completed on iPSCs, the research on hESCs must continue in order to develop meaningful comparisons between the two types of cells and their potential benefits to medical research.<sup>28</sup> In the meantime, the medical significance of this research demands that we “simultaneously pursue all lines of research.”<sup>29</sup> Human embryonic stem cells provide a novel way to conduct early stage screening for new drugs and “may hold the

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<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Stem Cell Information: Stem Cell Basics*, *supra* note 1, at 8.

<sup>24</sup> *Id.* at 3, 22.

<sup>25</sup> *Id.*

<sup>26</sup> *Id.* at 3.

<sup>27</sup> *Hearing*, *supra* note 20, at 5 (statement of Dr. Francis Collins, Director, National Institutes of Health).

<sup>28</sup> *Stem Cell Information: Stem Cell Basics*, *supra* note 1, at 13–14. iPSC research is not yet a substitute for embryonic stem cell research. Latham, *supra* note 17, at 492. Researchers are still discovering the mechanism behind pluripotency and exploring the differences between iPS cells and hES cells. *Id.*

<sup>29</sup> *Stem Cell Information: Frequently Asked Questions*, *supra* note 6.

secrets to creating entirely new targeted clinical therapies.”<sup>30</sup> Developments in the public and private sector, including the first Food and Drug Administration (“FDA”) approved trial involving the use of hESCs, demonstrate that the need for hESCs in biomedical research is, and will remain, of significant importance for the foreseeable future.<sup>31</sup>

### III. THE LAW AND EMBRYONIC STEM CELLS

#### A. *A Brief History of the Dickey-Wicker Amendment*

The Dickey-Wicker Amendment was first added to the Balanced Budget Downpayment Act of 1996<sup>32</sup> and has been reenacted without “substantial alteration”<sup>33</sup> every year since as part of the Health and Human Services Appropriations bill.<sup>34</sup> The relevant language states that federal funding will not support:

- (1) the creation of a human embryo or embryos for research purposes; or
- (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero . . . .<sup>35</sup>

Simply put, federal agencies may not fund research that will result in the creation or destruction of embryos. This section of the

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<sup>30</sup> Francis Collins, *NIH Director’s Response to Stem Cell Injunction*, NAT’L INSTS. HEALTH (Aug. 26, 2010), [http://www.nih.gov/about/director/08262010statement\\_stemcellinjunction.htm](http://www.nih.gov/about/director/08262010statement_stemcellinjunction.htm).

<sup>31</sup> *Geron Receives FDA Clearance to Begin World’s First Human Clinical Trial of Embryonic Stem Cell-Based Therapy*, GERON (Jan. 23, 2009), <http://www.geron.com/media/pressview.aspx?id=1148>.

<sup>32</sup> Balanced Budget Downpayment Act of 1996, Pub. L. No. 104-99, 110 Stat. 26.

<sup>33</sup> *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 67 (D.D.C. 2010) (citing Omnibus Appropriations Act 2009, Pub. L. No. 111-8, § 509(a)(2), 123 Stat. 524, 803 (2009)).

<sup>34</sup> *Id.*

<sup>35</sup> Omnibus Appropriations Act 2009, Pub. L. No. 111-8, § 509, 123 Stat. 524, 803 (2009). This section goes on to define a human embryo as “any organism, not protected as a human subject under 45 C.F.R. § 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.” *Id.* at § 509 (b).

appropriations bill is known as an appropriations rider,<sup>36</sup> and is commonly used to limit the funding that federal agencies may use for specific purposes.<sup>37</sup> Limitation riders such as the Amendment can be controversial because they do not involve the same review process as substantive legislation passed by Congress that directly bans agency action.<sup>38</sup>

Human stem cell research took off in earnest in 1998 when Dr. James Thomson's method of isolating stem cells was developed.<sup>39</sup> This development occurred two years after the Amendment was signed into law.<sup>40</sup> The Amendment has been passed every year since 1996 without "substantial alteration"<sup>41</sup> as part of the Health and Human Services appropriations bill.<sup>42</sup> Given the timeline, proponents of hESC research will argue that the Amendment was not passed with the specific intention of limiting hESC research.<sup>43</sup>

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<sup>36</sup> Ryan Fujikawa, *Federal Funding of Human Embryonic Stem Cell Research: An Institutional Examination*, 78 S. CAL. L. REV. 1075, 1083 (2005).

<sup>37</sup> This type of appropriations rider is known as a "limitation rider." Neal E. Devins, *Regulation of Government Agencies Through Limitation Riders*, 1987 DUKE L.J. 456, 461 (1987) ("One of the most controversial and frequently used devices of appropriations-based oversight of executive action is the limitation rider.").

<sup>38</sup> *Id.* at 458 ("The use of the appropriations process to accomplish substantive objectives that have not been considered previously or that contravene established statutory objectives may prevent the appropriate authorizing committee from applying its expertise. Exacerbating this problem, appropriations are often acted on quickly, providing little opportunity for thoughtful deliberation of the issues raised by such measures.").

<sup>39</sup> James Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, SCIENCE, Nov. 6, 1998, at 1145.

<sup>40</sup> "Scientists have only been able to do experiments with human embryonic stem cells (hESCs) since 1998, when a group led by Dr. James Thomson at the University of Wisconsin developed a technique to isolate and grow the cells." *Stem Cell Information: Frequently Asked Questions*, *supra* note 6.

<sup>41</sup> *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 67 (D.D.C. 2010) (citing Omnibus Appropriations Act 2009, Pub. L. No. 111-8, § 509(a)(2), 123 Stat. 524, 803 (2009)).

<sup>42</sup> *Sherley*, 704 F. Supp. 2d at 67.

<sup>43</sup> In passing the Amendment, Congress was reacting to a 1994 NIH panel that recommended funding for research on human embryos that would improve *in vitro* fertilization techniques. Brief for Appellants at 11, *Sherley v. Sebelius*, 704 F. Supp. 2d 63, (D.C. Cir. 2010) (No. 10-5287) (citing NIH, Report of the



However, opponents have a strong argument that the Amendment was passed with the intention of regulating the use of federal funds for research that was not yet in existence, but could involve human embryos.<sup>44</sup>

The Amendment can be interpreted to ban all research activity that will result in the destruction of human embryos.<sup>45</sup> After stem cells were first derived from embryos, a process that necessarily destroys the embryo,<sup>46</sup> the NIH requested guidance from the U.S. Department of Health and Human Services (“HHS”) regarding funding of embryonic stem research.<sup>47</sup> In 1999, near the end of the Clinton Administration, HHS legal counsel Harriet S. Rabb wrote a memorandum on behalf of HHS, which concluded that the Amendment did not ban the use of federal funds to conduct hESC research.<sup>48</sup> Ms. Rabb made a distinction between the use of human embryos and the use of human embryonic stem cell lines for research purposes:<sup>49</sup>

Pluripotent [embryonic] stem cells are not organisms and do not have the capacity to develop into an organism that could perform all the life functions of a human being. They are, rather, human cells that have the potential to evolve into different types of cells such as blood cells or insulin-producing cells . . . . Pluripotent stem cells do not have the capacity to develop into a human being, even if transferred to a uterus

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Human Embryonic Research Panel 75–76 (1994), *available at* [http://bioethics.georgetown.edu/pcbe/reports/past\\_commissions/index.html](http://bioethics.georgetown.edu/pcbe/reports/past_commissions/index.html).

<sup>44</sup> *Hearing*, *supra* note 20 (statement of Sen. Roger Wicker). Senator Wicker was a coauthor of the Dickey-Wicker Amendment when he was a member of the House of Representatives in 1995. *Id.* He testified at the most recent hearing on stem cell research to support a ban on using federal funding for human embryonic stem cell research. *Id.* Senator Wicker maintains that “the body of evidence developed since 1995 has served only to strengthen the argument in favor of Dickey-Wicker.” *Id.*

<sup>45</sup> Judge Lamberth came to this conclusion when holding that the language of the Dickey-Wicker Amendment is unambiguous. *See Sherley*, 704 F. Supp. 2d at 71.

<sup>46</sup> *See id.* at 67.

<sup>47</sup> Diane T. Duffy, *Background and Legal Issues Related to Stem Cell Research*, ALMANAC OF POLICY ISSUES, [http://www.policyalmanac.org/health/archive/crs\\_stem\\_cell.shtml](http://www.policyalmanac.org/health/archive/crs_stem_cell.shtml) (last modified June 12, 2002).

<sup>48</sup> *Id.*

<sup>49</sup> *Id.* (citing Memorandum from HHS Gen. Counsel Harriet Rabb to Harold Varmus, Dir., NIH (Jan. 15, 1999)).

Field Code Changed

Field Code Changed

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.... Based on an analysis of the relevant law and scientific facts, federally funded research that utilizes human pluripotent stem cells would not be prohibited by the HHS appropriations law [Dickey-Wicker Amendment] prohibiting human embryo research, because such stem cells are not human embryos.<sup>50</sup>

With this interpretation of the law, it was assumed that the federal government could legally fund research on embryonic stem cell lines,<sup>51</sup> as long as they did not actually fund derivation of the original stem cells from the embryo.<sup>52</sup>

In 2001, President Bush issued an executive order seeking to limit federal funding of embryonic stem cell research.<sup>53</sup> Under the new presidential policy, federal funds could be used to support hESC research only on stem cell lines already in existence, which precluded using federal funds on any new stem cell lines.<sup>54</sup> While President Bush's policy did indeed limit the "destruction" of human embryos, it also impliedly adopted the interpretation of the Dickey-Wicker Amendment set out by the Rabb memorandum, making it legal for the federal government to spend taxpayer dollars on research of hESC lines as long as that money did not go specifically to the derivation of the stem cells.<sup>55</sup>

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<sup>50</sup> Memorandum from HHS Gen. Counsel Harriet Rabb to Harold Varmus, Dir., NIH (Jan. 15, 1999).

<sup>51</sup> The key distinction is that embryonic stem cell lines are technically different from embryos. "A stem cell line is a family of constantly-dividing cells, the product of a single parent group of stem cells. They are obtained from human or animal tissues and can replicate for long periods of time *in vitro*." *Extended Definition: Stem Cell Line*, WEBSTERS ONLINE DICTIONARY, <http://www.websters-online-dictionary.org/definitions/Stem+cell+line> (last visited Sept. 27, 2010).

<sup>52</sup> See Gardiner Harriss & Sheryl Gay Stolberg, *Stem Cell Ruling Will Be Appealed*, THE N.Y. TIMES (Aug. 24, 2010), <http://www.nytimes.com/2010/08/25/health/policy/25stem.html>.

<sup>53</sup> Exec. Order No. 13,435, 3 C.F.R. 222 (2008).

<sup>54</sup> George W. Bush, *Address to the Nation on Stem Cell Research From Crawford, Texas*, 37 WEEKLY COMP. PRES. DOC. 1149 (Aug. 9, 2001); see also *NIH Human Embryonic Stem Cell Registry Under Former President Bush* (Aug. 9, 2001–Mar. 9, 2009), NAT'L INSTS. HEALTH, <http://stemcells.nih.gov/research/registry/eligibilitycriteria> (last modified Mar. 9, 2009).

<sup>55</sup> See Bush, *supra* note 54.

Field Code Changed

Field Code Changed

On March 9, 2009, President Obama issued an executive order that revoked the limitations to hESC research set out by the Bush Administration.<sup>56</sup> The new policy called for additional hESC lines to be introduced into the NIH stem cell registry and for the NIH to issue new guidelines that would promote the use of stem cell lines derived from excess embryos that would otherwise be discarded from *in vitro* fertilization procedures.<sup>57</sup> The new NIH Guidelines for Human Stem Cell Research (“Guidelines”) took effect on July 7, 2009.<sup>58</sup> The Guidelines remained consistent with the standing interpretation of the Dickey-Wicker Amendment: federal funding would not go towards the actual derivation of embryos but would fund research on hESC lines.<sup>59</sup>

At the time Obama’s executive order was implemented, Congress and the Executive Branch had been operating under the Rabb interpretation of the Amendment for ten years.<sup>60</sup> The general perception was that the federal government could fund research on hESCs as long as the money did not go directly towards the derivation process that would destroy the embryos. This settled interpretation was brought into question when two scientists who specialize in adult stem cell research challenged the new NIH Guidelines.<sup>61</sup>

#### B. *The Holding and Impact of Sherley v. Sebelius*

On August 23, 2010, Judge Royce Lamberth of the Federal District Court for the District of Columbia enjoined the NIH from

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<sup>56</sup> Exec. Order No. 13,505, 74 Fed. Reg. 10667 (Mar. 9, 2009).

<sup>57</sup> *Id.*

<sup>58</sup> NIH Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32170 (July 7, 2009).

<sup>59</sup> *But see* *Sherley v. Sebelius*, No. 09-1575 (D.C. Cir.), stay denied Aug. 31, 2010) (“The prior guidelines, of course, allowed research only on existing stem cell lines, foreclosing additional destruction of embryos.”).

<sup>60</sup> Congress has continually passed the Amendment, even though they were aware that the NIH and other institutions used federal monies to do research on human embryonic stem cell lines.

<sup>61</sup> Drs. James Sherley and Theresa Diescher are plaintiffs in the case who conduct non-embryonic stem cell research and claim that funding of hESC harms them. *See* *Sherley v. Sebelius*, 704 F. Supp. 2d 63 (D.D.C. 2010).

implementing the new Guidelines,<sup>62</sup> as authorized by Obama's executive order entitled *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*.<sup>63</sup> Drs. James Sherley and Theresa Deischer, Nightlight Christian Adoptions, Embryos, prospective adoptive parents, and the Christian Medical Association originally brought the suit to enjoin defendants from implementing the Guidelines or otherwise funding research that involves the destruction of hESCs.<sup>64</sup> The district court dismissed the suit on the basis that plaintiffs lacked standing.<sup>65</sup> The Court of Appeals reversed and remanded, finding that Drs. Sherley and Deischer did have standing based on the competitor standing doctrine.<sup>66</sup> On remand, Judge Lamberth found in favor of the plaintiffs and imposed a preliminary injunction blocking the NIH from implementing the new Guidelines.<sup>67</sup>

The holding reached by the district court prohibited the implementation of the Guidelines on the basis that they violated the plain language of the Dickey-Wicker Amendment.<sup>68</sup> The rationale for the decision follows a simple logical syllogism:

[Embryonic stem cell ("ESC")] research is clearly research in which an embryo is destroyed. To conduct ESC research, ESCs must be derived from an embryo. The process of deriving ESCs from an embryo results in the destruction of the embryo. Thus, ESC research necessarily depends upon the destruction of a human embryo.<sup>69</sup>

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<sup>62</sup> Guidelines, 74 Fed. Reg. at 32,170.

<sup>63</sup> *Sherley*, 704 F. Supp. 2d at 73.

<sup>64</sup> *Sherley v. Sebelius*, 686 F. Supp. 2d 1, 3 (D.D.C. 2009) *rev'd in part*, 610 F.3d 69 (D.C. Cir. 2010).

<sup>65</sup> *Id.* at 7.

<sup>66</sup> *Sherley v. Sebelius*, 610 F.3d 69, 74 (D.C. Cir. 2010) (stating "[b]ecause the Guidelines have intensified the competition for a share in a fixed amount of money, the plaintiffs will have to invest more time and resources to craft a successful grant application. That is an actual, here-and-now injury.").

<sup>67</sup> *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 73 (D.D.C. 2010).

<sup>68</sup> *Id.* at 71 (holding if hESC research is "research in which a human embryo is to be harmed or destroyed," the Guidelines violate the Dickey-Wicker Amendment).

<sup>69</sup> *Sherley*, 704 F. Supp. 2d at 71.

Essentially, Judge Lamberth found the distinction between research done on hESC lines and research that directly involves deriving the cells from the embryo to be immaterial.<sup>70</sup> He discounted the Rabb interpretation of the word “embryo” because it assumes the Dickey-Wicker Amendment is ambiguous.<sup>71</sup> To the contrary, Judge Lamberth found that the plain language of the Dickey-Wicker Amendment is unambiguous and explicitly bans all research involving the destruction of human embryos.<sup>72</sup>

The government filed an appeal along with a motion to stay the preliminary injunction.<sup>73</sup> After a denial from the district court, the Court of Appeals for the District of Columbia granted the motion and the injunction will be stayed until the appeal can be heard.<sup>74</sup> The stay gives the NIH and other institutions that depend on federal funding breathing room to continue critically important biomedical research until the merits of the case can be heard on appeal. However, it does not give scientists conducting long-term research experiments any certainty regarding funding that must be renewed every twelve months. This is especially troublesome in light of the fact that most embryonic stem cell research is long-term.<sup>75</sup> It may also discourage younger scientists from applying for new grants that involve the use of human embryonic stem cell lines.<sup>76</sup>

#### IV. CONGRESS AND STEM CELL RESEARCH

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<sup>70</sup> *Id.*

<sup>71</sup> *Id.* at 71–72.

<sup>72</sup> *Id.* at 72.

<sup>73</sup> *Stem Cell Reseach* [sic]: *Government Files Appeal, Seeks Stay Order in Case Halting Stem Cell Research Funding*, Biotech Watch Online (BNA) (Sep. 1, 2010).

<sup>74</sup> *Sherley v. Sebelius*, No. 10-5287, (D.C. Cir. Sept. 10, 2010) (granting stay).

<sup>75</sup> Embryonic stem cell research has been conducted since 1998 and it is only recently that the first FDA approved trial has begun. *See Geron Receives FDA Clearance to Begin World's First Human Clinical Trial of Embryonic Stem Cell-Based Therapy*, GERON (Jan. 23, 2009), <http://www.geron.com/media/pressview.aspx?id=1148>.

<sup>76</sup> *See Hearing*, *supra* note 20, at 4 (statement of George Q. Daley, M.D., Ph.D.).

A. *The Intent of Congress*

Judge Lamberth argued that the congressional intent outside the text of the Dickey-Wicker Amendment is irrelevant because the plain language of the Amendment is unambiguous.<sup>77</sup> Nonetheless, Judge Lamberth noted that Congress does not support the use of federal funds for hESC research because “Congress has included the Dickey-Wicker Amendment in every appropriations bill for Health and Human Services (“HHS”) since 1996 without substantive alteration.”<sup>78</sup> The debate over the ambiguity, or lack of ambiguity, in the language of the Dickey-Wicker Amendment is likely to be a major issue on appeal.

On one hand, Congress has passed the Dickey-Wicker Amendment every year since 1996 without making any attempt to narrow its language, despite the knowledge that advances in stem cell research involve the destruction of embryos in the initial phase of the research process.<sup>79</sup> On the other hand, it is clear that Congress has been fully aware of the state of stem cell research and has not taken action to reject the definition of “embryo” set by the Clinton Administration and adopted by the NIH in 2000.<sup>80</sup>

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<sup>77</sup> See *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 70. *Chevron* deference refers to a legal test that determines how much deference a court must grant to a government agency’s interpretation of a statute. If Congress speaks directly to the issue, the agency must give effect to the intent of Congress and the courts grant no deference to agency interpretation. The courts base their decision on the clear intent of Congress. When Congress has used ambiguous language, the courts grant deference to the agency’s interpretation of the statute. See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). The issue for this court is whether or not Congress’s intent is clear within the Dickey-Wicker Amendment standing on its own. If it is clear, then that is the end of the issue. If it is ambiguous, the court may grant deference to the interpretation adopted by the NIH Guidelines.

<sup>78</sup> *Sherley*, 704 F. Supp. 2d at 67–68 (citing Omnibus Appropriations Act 2009, Pub. L. No. 111-8, § 509, 123 Stat. 524, 803 (2009)).

<sup>79</sup> The Senate Appropriations Subcommittee on Labor, Health, and Human Services has held twenty-one hearings on embryonic stem cell research since December of 1998. See *Hearing*, *supra* note 20 (statement of Sen. Thomas Harkin).

<sup>80</sup> *Id.* Congress has acted with “full knowledge that HHS has been funding hESC research since 2001.” NIH Guidelines for Human Stem Cell Research, 74 Fed. Reg. 31,270, 32,173 (July 7, 2009).

Should congressional silence on this issue be seen as condoning or rejecting the Rabb interpretation? Although debatable, there is evidence that Congress has condoned the actions of the NIH. For example, in its memorandum to the court in support of the motion to stay the preliminary injunction, the government defendants argue that Congress has endorsed the interpretation that a distinction can be made between embryos and hESC lines:

Congress has done more than acquiesce in NIH's interpretation: it has expressly endorsed the view that hESC research is not barred by the Dickey-Wicker Amendment. In light of the endorsement by Congress of that rational, long-standing interpretation—an endorsement that was magnified by Congress's approval of the interpretation in the recent passage of the 2010 appropriations for NIH—defendants respectfully assert that their interpretation is consistent with . . . congressional intent.<sup>81</sup>

If it is indeed clear that Congress implicitly supports embryonic stem cell research, why has it exclusively relied on executive orders to define the parameters of such research since 2001? There seem to be two reasons an embryonic stem cell research bill has yet to become law: 1) two separate bills were passed by Congress during the Bush Administration and both subsequently vetoed, slowing momentum for further action;<sup>82</sup> and 2) Congress did not feel it imperative to amend the Dickey-Wicker Amendment when interpretation allowing human embryonic stem

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<sup>81</sup> Memorandum in Support of Defendants' Emergency Motion to Stay the Preliminary Injunction Pending Appeal and for Expedited Briefing and Consideration at 2, *Sherley v. Sebelius*, 704 F. Supp. 2d 63 (D.D.C. 2010) (No. 1:09-cv-01575-RCL).

<sup>82</sup> See The Stem Cell Research Enhancement Act of 2005, H.R. 810, 109th Cong. (2006). See also The Stem Cell Research Enhancement Act of 2007, S. 5, 110th Cong. (2007). The Stem Cell Research Enhancement Acts of 2005 and 2007 were bills passed by Congress and subsequently vetoed by President Bush. Both bills called for the support of human embryonic stem cell research, regardless of the date in which the stem cells were derived from the embryo. Additionally, both bills would have limited federal funding to the use of stem cell lines derived from embryos that would otherwise be discarded from *in vitro* fertilization clinics.

cell research appeared to be settled by long-standing practice.<sup>83</sup> Simply put, there has been a lack of political will to change the status quo. Now that the standing interpretation has been brought into question, it is the time for Congress to explicitly endorse the federal funding of embryonic stem cell research through new legislation. If Congress can successfully pass another bill supporting hESC research, as it did with the Stem Cell Enhancement Acts of 2005 and 2007, they can count on a different outcome since it is likely that President Obama would support such legislation.<sup>84</sup>

B. “*Sand into the Engine of Discovery*”

It is imperative that Congress changes the language of the Dickey-Wicker Amendment while there is an appeal pending and before the preliminary injunction can be reinstated. With the latest advances, including the start of an FDA-approved trial using hESCs,<sup>85</sup> it is more important than ever to secure funding for this type of research. Francis Collins, Director of the NIH and a named defendant in *Sherley*, stated in reference to the current state of hESC research, “[t]his is one of the most exciting areas of the broad array of engines of discovery that NIH supports. This decision has just poured sand into that engine of discovery.”<sup>86</sup>

In order to reverse the negative consequences the district court’s decision has had on the scientific community, Congress needs to amend or repeal the Dickey-Wicker Amendment. This would give scientists the confidence and stability necessary to pursue research that can potentially benefit those with currently incurable conditions. The decision in *Sherley* rested on the definition of the word “research” as definitively meaning “a

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<sup>83</sup> The NIH adopted the current interpretation of the Amendment in its guidelines issued in 2000. NIH Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976, 51,979 (Aug. 25, 2000).

<sup>84</sup> See Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

<sup>85</sup> See *Geron Receives FDA Clearance to Begin World's First Human Clinical Trial of Embryonic Stem Cell-Based Therapy*, GERON (Jan. 23, 2009), <http://www.geron.com/media/pressview.aspx?id=1148>.

<sup>86</sup> *Stem Cell Reseach* [sic], *supra* note 73.



systematic investigation.”<sup>87</sup> In the government’s memorandum to the U.S. Court of Appeals in support of a stay of the preliminary injunction, defendants’ counsel contests the overly-broad definition of the word “research” in favor of a more narrow definition or, in the alternative, reading the word “research” in context of the surrounding text.<sup>88</sup> While such textualism is common practice in the judicial arena, it gives the appearance of splitting hairs over something necessarily subjective and relatively insignificant.<sup>89</sup>

Potential clinical treatments involving stem cell research can take years to develop and serious commitment on the part of researchers in the field.<sup>90</sup> Given the social and political debate surrounding this issue and the high stakes of the research involved, it is probable that the loser at the appellate level will try to take the issue to the Supreme Court. This will likely be a long and drawn out process. To let this issue play out in the courts where opposing counsel will argue over the scope of the word “research” will result in a loss of confidence in the federal government.

Congress has had the opportunity to clarify the language of the Dickey-Wicker Amendment every fiscal year for over a decade, but has failed to do so in favor of permitting the long-standing agency interpretation. The Rabb memorandum presented a way for HHS and the NIH to fund critical research in the face of an explicit appropriations limitation. However, an agency’s adoption of a legal opinion does not have the same force as direct congressional action. At this point, only the courts or the

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<sup>87</sup> *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 70 (D.D.C. 2010)

<sup>88</sup> Memorandum in Support of Defendants’ Motion to Dismiss, and in Opposition to Plaintiffs’ Motion for Preliminary Injunction at 31–32, *Sherley v. Sebelius*, 704 F. Supp. 2d 63 (D.D.C. 2010) (No. 1:09-cv-01575-RCL).

<sup>89</sup> “Textualism is a formalist theory of statutory interpretation which holds that a statute’s ordinary meaning should govern its interpretation, as opposed to inquiries into non-textual sources such as the intention of the legislature in passing the law, the problem it was intended to remedy, or substantive questions of the justice and rectitude of the law.” *Extended Definition: Textualism*, WEBSTERS ONLINE DICTIONARY, <http://www.websters-online-dictionary.org/definitions/textualism> (last visited Sept. 27, 2010).

<sup>90</sup> See *Hearing*, *supra* note 20, at 8 (statement of Dr. Francis Collins, Director, National Institutes of Health).

legislature have the authority to decide if the new Guidelines can be implemented. As a matter of policy, this is more appropriately settled by the legislature where it can be debated and viewed as a whole issue rather than as a matter of statutory interpretation.

*C. Congress Should Pass a Comprehensive Stem Cell Bill*

In addition to narrowing the Dickey-Wicker Amendment, Congress should pass a bill that will expressly state its intentions regarding embryonic stem cell research. Preferably, such a bill will codify President Obama's executive order and open the door to a transparent set of rules that will regulate future hESC research. There is already a bill in Committee that would accomplish this objective. The Stem Cell Research Advancement Act of 2009<sup>91</sup> was introduced to the House of Representatives on March 10, 2010, one year after President Obama's executive order was signed.<sup>92</sup>

On September 13, 2010, a companion bill was introduced to the Senate, similarly titled the Stem Cell Research Advancement Act of 2010.<sup>93</sup> These bills call for the support of stem cell research, explicitly including embryonic stem cell research where the stem cells were derived from excess embryos donated from *in vitro* fertilization clinics.<sup>94</sup> Additionally, the bills require that a consultation with the donors be conducted to ensure that the embryos would otherwise be discarded and those individuals donating their embryos provide written, informed consent without receiving financial or other inducement.<sup>95</sup> The legislation would require the NIH to maintain guidelines and update them every three years or as "scientifically warranted."<sup>96</sup> These provisions, if

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<sup>91</sup> Stem Cell Research Advancement Act of 2009, H.R. 4808, 111th Cong. (2010).

<sup>92</sup> *Stem Cell Research: Embryonic Stem Cell Research Legislation Introduced to Codify Obama Executive Order*, Biotech Watch Online (BNA) (Mar. 12, 2010).

<sup>93</sup> Stem Cell Research Advancement Act of 2010, S. 3766, 111th Congress, (2010).

<sup>94</sup> See *id.* § 498(E); see also H.R. 4808, § 498(D).

<sup>95</sup> S. 3766 § 498(E); H.R. 4808, § 498(D).

<sup>96</sup> See S. 3766, § 498(F); see also H.R. 4808, § 498(E).

enacted, would provide a codification of President Obama's executive order.

The only notable difference between the bills is that the more recent Senate bill explicitly states that this act shall not supersede section 509 of the most recent HHS appropriations bill.<sup>97</sup> This is a direct reference to the language of the Dickey-Wicker Amendment restricting funding of research that results in the destruction of embryos. Both the House and Senate bills would amend the Public Health Service Act<sup>98</sup> "[n]otwithstanding any other provision of law," so technically the additional language found in the Senate bill would make no applicable difference.<sup>99</sup> However, the new language does evidence the Senate's intent to comply with the Dickey-Wicker Amendment. In order for this bill to have its intended effect, the appellate courts will have to uphold the Rabb interpretation of the Dickey-Wicker Amendment.<sup>100</sup> The Rabb interpretation is essentially a legal workaround that should not serve as a permanent solution, but rather should have worked as merely a stopgap until Congress could act.

Congress should make it a priority to get this legislation through committee and onto the floor for debate. Also, those representatives who support stem cell research should make it a goal to amend the Dickey-Wicker Amendment to allow for research on pre-implantation stage embryos obtained under the ethical boundaries set forth in the Act. The Bush Administration succeeded in delaying important research, and President Obama tried to reverse the policy through an executive order. Unfortunately, with the recent court ruling, the Obama

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<sup>97</sup> S. 3766, § 498(E) (stating "[n]otwithstanding any other provision of law, including section 509 of division D of the Consolidated Appropriations Act, 2010 or any substantially similar provision in any previous or subsequent Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act . . .").

<sup>98</sup> Public Health Service Act, 42 U.S.C. § 289 (2006).

<sup>99</sup> S. 3766, § 498(E); H.R. 4808, § 498(D).

<sup>100</sup> That is the Court of Appeals would have to find that human embryonic stem cells are not the same as human embryos for the purpose of medical research. See Memorandum from HHS Gen. Counsel Harriet Rabb to Harold Varmus, Dir., NIH (Jan. 15, 1999).

Administration's effort may fail. Relying on the appellate process to vindicate the agency interpretation of the Amendment is a gamble. The more appropriate solution is to have our elected representatives pass legislation that will reassure the research community of continued funding.

## V. CONCLUSION

The decision in *Sherley v. Sebelius* is a setback for potentially life-saving medical research. Public funding of embryonic stem cell research benefits the public welfare. Therefore, Congress should take action that will explicitly support this type of research. In this economy, the absence of public funding could truly hinder further medical breakthroughs involving human embryonic stem cells. Judge Lamberth rested his holding in the case on the language of the Dickey-Wicker Amendment. The Amendment, which was added to the appropriations bill before embryonic stem cells could be isolated and grown in culture, is outdated and should be narrowed to allow for research that has been implicitly approved by Congress and the Executive Branch for over ten years. Furthermore, Congress should finally pass a stem cell bill that reflects the executive order issued by President Obama in 2009. Scientists still have a lot to learn from studying human embryonic stem cells, and we should allow those scientists the opportunity to decide which cells to study and to what extent.<sup>101</sup> American scientists should have the best opportunity to follow through on the promising research they have been conducting and an incentive to continue with progressive research. Otherwise, the denial of federal funds could mean the denial of hope for many Americans struggling with debilitating diseases.

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<sup>101</sup> See *Hearing, supra* note 20, at 2 (statement of Dr. George Q. Daley, M.D., PhD).

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